REMARKS

In view of the above amendments and the following remarks, reconsideration and further examination are respectfully requested.

Status of All of the Claims

Claims 25-47 are pending, with claims 25 and 28 being independent. Claims 1-24 have been cancelled. Claims 25-47 have been added. No new subject matter has been added.

Claim Support

It is believed that the new and amended claims are supported by the application as originally filed. This application is a 371 national stage application of International Application No. PCT/EP2004/005924. During the international phase, Article 19 amendments were filed in which new claims 1-23 replaced the original claims 1-24. In the previous Restriction Requirement and response, it appears that the originally-filed claims (1-24) were being prosecuted instead of the claims from the Article 19 amendment (claims 1-23). To address this issue, claims 1-24 have been canceled and replaced with claims that generally correspond to those made in the Article 19 amendment of February 21, 2005 (i.e., claims 1-23). The claims have been further amended to further highlight the distinguishing features as will be discussed below and have also been modified to address the informalities cited in item 4 of the Office Action. It is believed the claims are supported by the application as originally filed and the currently-pending claims correspond to those elected during the previous Restriction Requirement. For example, support for the above-identified new claims can at least be found in FIG. 2 of the drawings and paragraph 52 of the specification.

Independent Claim 25

It is believed that new independent claim 25 is distinguishable from the cited references. In particular, none of the cited references anticipate and/or render obvious claim 25.

For example, it is believed that independent claim 25 is not anticipated by the Coleman reference (US 4,622,974). Coleman generally concerns a blunt interior needle 28 that is positioned within a larger external needle. Looking at FIGS. 2a-c, reproduced below, the interior needle 28 has a blunt end with a reflective surface 30 or gold foil 36 that is mounted on the blunt

end of the needle 28 that functions as a reflective surface. The reflective surface (or the gold foil) reflects light back onto the optical fiber 16 such that fluid samples can be analyzed. In one example, illustrated in FIG. 1a and as discussed in Col. 7, starting at line 53, "a reagent may be immobilized within the sample cavity 36 so that the reagent is inserted along with the probe into the region of the biological fluids to be tested."

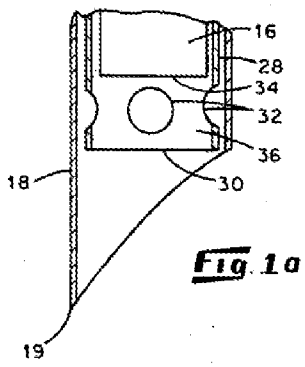

Fig. 1a

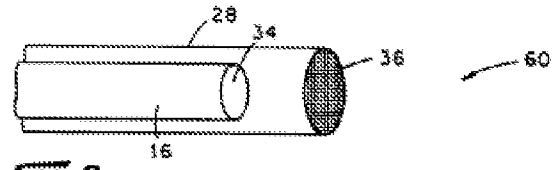

Fig. 2a

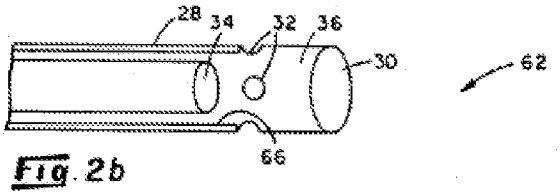

Fig. 2b

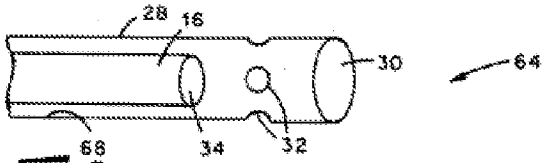

Fig. 2c

As should be appreciated from reviewing new independent claim 25, it includes a number of features neither disclosed nor suggested by the Coleman reference. For example, Coleman fails to disclose "a distal end on which the test field is coated" as is recited in claim 25. At most, Coleman discloses the reagent to be in the sample cavity, but it does not disclose that the distal end of the optical fiber 16 is coated with a reagent. Moreover, coating the reagent on the optical fiber would change the principle operation of the apparatus in Coleman because the light would not be able to be reflected off the reflecting surface 30 for testing purposes because the light would be blocked by the reagent coated on the end.

As another example, Coleman fails to disclose "wherein the lancet has an opening that enables the test field on the distal end of the light-conducting element to protrude beyond the lancet tip for contacting the sample." As mentioned before, the end of the blunt needle 28 is enclosed either with a reflective surface 30 or a gold foil 36. Thus, the optical fiber 16 in Coleman is unable to extend through an opening.

The other remaining references fail to remedy this feature. For example, Garcia (US 4,627,445) fails to remedy these features as well as others. As illustrated in FIG. 4, reproduced below, the reagent strip 94 in Garcia is located on the end of the needle 90 and is not coated on the phototransistor 52. Moreover, the phototransistors are unable to extend through the needle and therefore lack the opening as recited in independent claim 25.

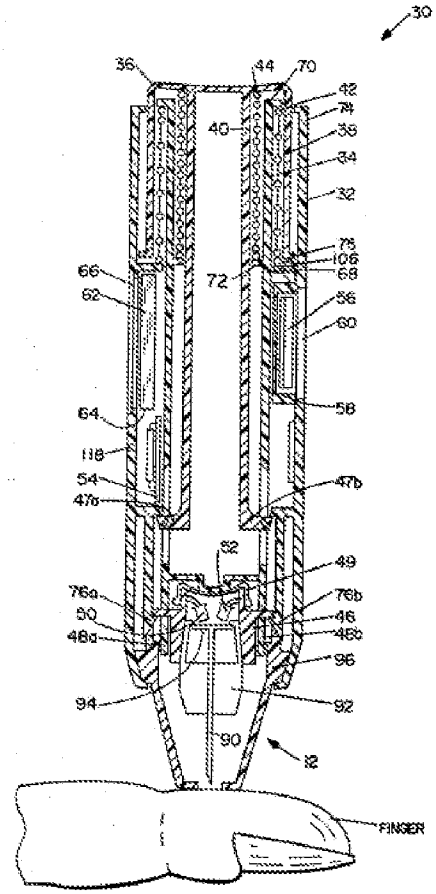

FIG. 4

As another example, looking at FIG. 9 of Staehlin (US 5,636,640), which is reproduced below, an infrared source 41 and a detector 42 are located above and below the reservoir 20.

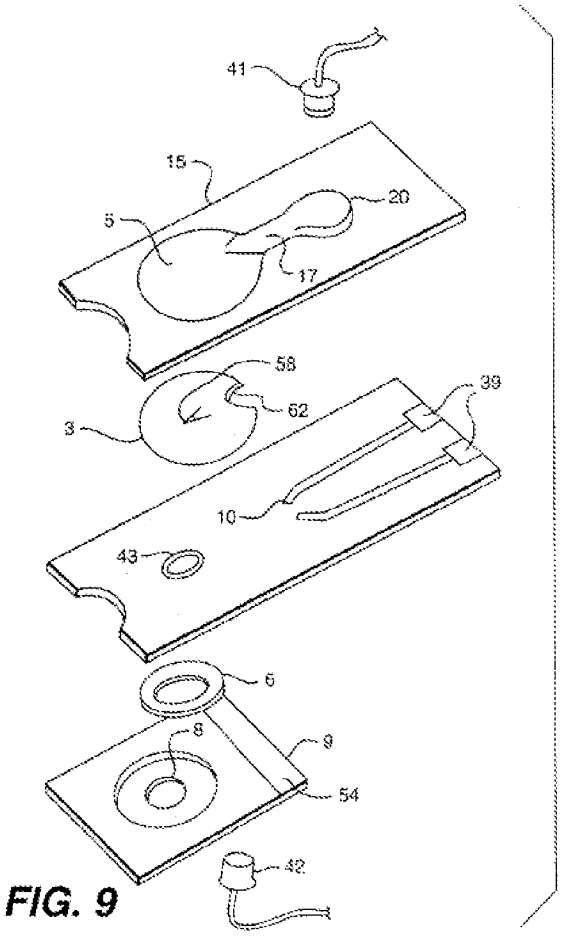

FIG. 9

The infrared light 41 can radiate through an opening 58 that is created by the shearing and forming operation used to form the protruding sharpened tip 56 in the piercer disk 3. The infrared source 41 and the detector 42 are used to determine the extent of blood coagulation.

As should be recognized in Staehlin, there is no light-conducting element let alone one positioned in the lancet that has a reagent on its distal tip. For these and other reasons, it is submitted that new independent claim 25 and its dependent claims are allowable over the references of record.

New Independent Claim 28

New independent claim 28 has been added to provide additional protection and again, generally corresponds to those previously presented with the Article 19 amendment with the exception that it includes some additional features to address the informalities cited in item 4 of the Office Action as well as to provide further points of distinction. As should be recognized, none of the references as discussed above disclose "wherein the lancet has an opening that enables the test field on the distal end of the light-conducting element to protrude beyond the lancet tip for contacting the sample" as is recited in claim 28. Again, the blunt interior needle 28 of Coleman lacks any type of opening through which the optical fiber 16 extends. Likewise, the other remaining references, such as Garcia and Staehlin, fail to disclose this particular feature. For these and other reasons, it is submitted that independent claim 28 and its dependent claims are in condition for allowance.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action, but are simply provided to overcome the rejections made in the Office Action in the most expedient fashion. In view of the above amendments and remarks, it is respectfully submitted that the present application is in condition for allowance and an early notice of allowance is earnestly solicited.

If after reviewing this amendment the Examiner feels that any issues remain which must be resolved before the application can be passed to issue, the Examiner is invited to contact the undersigned representative by telephone to resolve such issues.

Respectfully submitted,

By /Charles P. Schmal #45,082/

Charles P. Schmal, Reg. No. 45082
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
Telephone (317) 634-3456 Fax (317) 637-7561
Email: cschmal@uspatent.com